FDA Public Health Notification: MRI-Caused Injuries in Patients with Implanted Neurological Stimulators

(You are encouraged to copy and distribute this information)

Issued: May 10, 2005

This is to remind radiology personnel and physicians that serious injury or death can occur when patients with implanted neurological stimulators undergo MRI procedures, and to recommend preventive actions.

Background

The FDA has received several reports of serious injury, including coma and permanent neurological impairment, in patients with implanted neurological stimulators who underwent magnetic resonance imaging (MRI) procedures. The mechanism for these adverse events is likely to involve heating of the electrodes at the end of the leadwires, resulting in injury to the surrounding tissue. Although these reports involved deep brain stimulators and vagus nerve stimulators, similar injuries could be caused by any type of implanted neurological stimulator, such as spinal cord stimulators, peripheral nerve stimulators, and neuromuscular stimulators.

Recommendations

If you are a physician who implants or monitors patients with implanted neurological stimulators:

- Explain to the patient what MRI procedures are and stress that they must consult with the monitoring physician before having any MRI exam to find out whether it can be performed safely.

If you are a radiologist or health care professional who uses MRI equipment:

- All patients should be carefully screened for any implanted devices prior to performing an MRI procedure, ***even if the implanted device has been turned off***. Also question patients about previously implanted devices that have been removed. Leads, or portions of leads, often remain in the body after pulse generators are removed, and these may act as an antenna and become heated.
- If the patient does have an implanted neurological stimulator, consider consulting with the referring physician to discuss other imaging options. For some implanted neurological stimulators, certain MRI procedures are contraindicated and cannot be performed.

- If an MRI procedure is to be performed on a patient with an implanted neurological stimulator, be sure to review the labeling for the specific model that is implanted in the patient, with particular attention to warnings and precautions. The radiologist may need to consult with the implanting or monitoring physician for this information. Also note and follow any instructions exactly for MRI imaging that may be in the labeling for the implant, including information on types and/or strengths of MRI equipment that may have been tested for interaction with the particular implanted device. The radiologist may need to consult with the device implant manufacturer for this information.

Reporting Adverse Events

FDA requires hospitals and other user facilities to report deaths and serious injuries associated with the use of medical devices. If you suspect that a reportable adverse event has occurred involving a patient with an implanted device who has undergone an MRI procedure, you should follow the reporting procedure established by your facility.

We also encourage you to report adverse events related to MRI and medical devices that do not meet the requirements for mandatory reporting. You can report these directly to the device manufacturer. You can also report these events to MedWatch, the FDA's voluntary reporting program. You may submit reports to MedWatch by phone at 1-800-FDA-1088; by FAX at 1-800-FDA-0178; by mail to MedWatch, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857-9787; or online at http://www.fda.gov/medwatch/report.htm.

Getting More Information

If you have questions about this notification, please contact Nancy Pressly, Office of Surveillance and Biometrics (HFZ-510), 1350 Piccard Drive, Rockville, Maryland, 20850, Fax at 301-594-2968, or by e-mail at phann@cdrh.fda.gov. You may also leave a voice mail message at 301-594-0650 and we will return your call as soon as possible.

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Sincerely yours,

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